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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,542	05/26/2005	Roger Petrus Gerebern Vandecruys	PRD2017USPCT	7079

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EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/20/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/536,542	VANDECRUYS ET AL.	
	Examiner	Art Unit	
	JAKE VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-67* is/are pending in the application.

4a) Of the above claim(s) *43-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Request for Continued Examination and Amendment filed on 02/09/2011.

- Claims 21-67 are pending in the instant application.
- Claims 43-67 have been previously withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/09/2011 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-40 recites the limitation "according to claim 1", wherein claims 41-42 are dependent on claim 40. There is insufficient antecedent basis for this limitation in the claims, since claim 1 has been cancelled.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of U.S. Patent No. 7,241,458 **are maintained** for reasons of record in the previous office action filed on 07/22/2010, 11/09/2010 and as discussed below.

Claims 21-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of U.S. Patent No. 7,037917 **are maintained** for reasons of record in the previous office action filed on 07/22/2010, 11/09/2010 and as discussed below.

Claims 21-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of U.S. Patent No. 6,878,717 **are maintained** for reasons of record in the previous office action filed on 07/22/2010, 11/09/2010 and as discussed below.

Claims 21-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of copending Application No. 11/930,835 **are maintained** for reasons of record in the previous office action filed on 07/22/2010, 11/09/2010 and as discussed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

> applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-29, 31, 32, 34-42 are rejected under 35 U.S.C. 102(a,e) as being anticipated by CHEN et al (6,919,370; hereinafter "CHEN1") as evidence by FAIS et al (US 2008/0160106) and CASODEX (Drug Information at http://www.rxlist.com/casodex-drug.htm (2009)) **are maintained** for reasons of record in the previous office action filed on 07/22/2010, 11/09/2010 and as discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-29, 31, 32, 34-42 are rejected under 35 U.S.C. 102(a,e) as being anticipated by CHEN1 et al (6,919,370; hereinafter "CHEN1") as evidence by FAIS et al (US 2008/0160106) and CASODEX (Drug Information at http://www.rxlist.com/casodex-drug.htm (2009)) **are maintained** for reasons of record in the previous office action filed on 07/22/2010, 11/09/2010 and as discussed below.

Claims 21-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of VERRECK et al (WO

01/22938) **are maintained** for reasons of record in the previous office action filed on 07/22/2010, 11/09/2010 and as discussed below.

Response to Arguments

Applicant argues that Chen I does not anticipate the presently claimed invention because there is no disclosure of every limitation of the claims "arranged or combined in the same way as recited in the claim". Moreover, Chen I does not enable the presently claimed invention and therefore, cannot anticipate the presently claimed invention. The Examiner points to column 7, lines 19-22 to argue that Chen I "specifically teaches" a formulation using other cancer drugs, such as cisplatin. The cited passage, however, merely presents a laundry list of compounds.

The Examiner finds this argument unpersuasive, because Applicant's limitation of "a basic drug compound" encompass a broad spectrum of drugs, such as (see specification at paragraphs) [0229] other suitable drug compounds in the compositions of the present invention are [0230] analgesic and anti-inflammatory drugs (NSAIDs, fentanyl, indomethacin, ibuprofen, ketoprofen, nabumetone, paracetamol, piroxicam, tramadol, COX-2 inhibitors such as celecoxib and rofecoxib); [0231] anti-arrhythmic drugs (procainamide, quinidine, verapamil); [0232] antibacterial and antiprotozoal agents (amoxicillin, ampicillin, benzathine penicillin, benzylpenicillin, cefaclor, cefadroxil, cefprozil, cefuroxime axetil, cephalexin, chloramphenicol, chloroquine, ciprofloxacin, clarithromycin, clavulanic acid, clindamycin, doxyxycline, erythromycin, flucloxacillin sodium, halofantrine, isoniazid, kanamycin sulphate, lincomycin, mefloquine,

minocycline, nafcillin sodium, nalidixic acid, neomycin, norfloxacin, ofloxacin, oxacillin, phenoxymethyl-penicillin potassium, pyrimethamine-sulfadoxime, streptomycin); [0233] anti-coagulants (warfarin); [0234] antidepressants (amitriptyline, amoxapine, butriptyline, clomipramine, desipramine, dothiepin, doxepin, fluoxetine, reboxetine, amineptine, selegiline, gepirone, imipramine, lithium carbonate, mianserin, milnacipran, nortriptyline, paroxetine, sertraline; 3-[2-[3,4-dihydrobenzofuro[3,2-c]pyridin-2(1H)-yl]ethyl]-2-methyl-4H-pyri- do[1,2-a]pyrimidin-4-one); [0235] anti-diabetic drugs (glibenclamide, metformin, RWJ-394718, RWJ-394720, RWJ-666589, RWJ-37082), [0236] anti-epileptic drugs (carbamazepine, clonazepam, ethosuximide, gabapentin, lamotrigine, levetiracetam, phenobarbitone, phenytoin, primidone, tiagabine, topiramate, valpromide, vigabatrin); [0237] antifungal agents (amphotericin, clotrimazole, econazole, fluconazole, flucytosine, griseofulvin, itraconazole, ketoconazole, miconazole nitrate, nystatin, terbinafine, voriconazole, echinocandins); [0238] antihistamines (astemizole, cinnarizine, cyproheptadine, decarboethoxyloratadine, fexofenadine, flunarizine, levocabastine, loratadine, norastemizole, oxatomide, promethazine, terfenadine, cetirizine); [0239] anti-hypertensive drugs (captopril, enalapril, ketanserin, lisinopril, minoxidil, prazosin, ramipril, reserpine, terazosin); [0240] anti-muscarinic agents (atropine sulphate, hyoscine); [0241] antineoplastic agents and antimetabolites (platinum compounds, such as cisplatin, carboplatin; taxanes, such as paclitaxel, docetaxel; tecans, such as camptothecin, irinotecan, topotecan; vinca alkaloids, such as vinblastine, vindecine, vincristine, vinorelbine; nucleoside derivatives and folic acid antagonists such as 5-fluorouracil, capecitabine, gemcitabine, mercaptopurine,

thioguanine, cladribine, methotrexate; alkylating agents, such as the nitrogen mustards, e.g. cyclophosphamide, chlorambucil, chlormethine, iphosphamide, melphalan, or the nitrosoureas, e.g. carmustine, lomustine, or other alkylating agents, e.g. busulphan, dacarbazine, procarbazine, thiotepa; antibiotics, such as daunorubicin, doxorubicin, idarubicin, epirubicin, bleomycin, dactinomycin, mitomycin; HER 2 antibody, such as trastuzumab; podophyllotoxin derivatives, such as etoposide, teniposide; farnesyl transferase inhibitors, e.g. zarnestra; anthrachinon derivatives, such as mitoxantron); imatinib; bortezomib; [0242] anti-migraine drugs (alniditan, naratriptan, sumatriptan, almotriptan); [0243] anti-Parkinsonian drugs (bromocryptine mesylate, levodopa, selegiline, rasagiline); [0244] antipsychotic, hypnotic and sedating agents (alprazolam, amisulpride, buspirone, chlordiazepoxide, chlorpromazine, clozapine, diazepam, flupenthixol, fluphenazine, flurazepam, 9-hydroxyrisperidone, lorazepam, mazapertine, olanzapine, oxazepam, pimozide, pipamperone, piracetam, promazine, risperidone, selfotel, seroquel, sertindole, sulpiride, temazepam, thiothixene, triazolam, trifluperidol, ziprasidone, zolpidem, bromperidol, fluperidol, haloperidol, quetiapine, aripiprazole); [0245] anti-stroke agents (lubeluzole, lubeluzole oxide, riluzole, aptiganel, eliprodil, remacemide); [0246] antitussive (dextromethorphan, laevodropropizine); [0247] antivirals (acyclovir, ganciclovir, loviride, tivirapine, zidovudine, lamivudine, zidovudine+lamivudine, didanosine, zalcitabine, stavudine, abacavir, lopinavir, amprenavir, nevirapine, efavirenz, delavirdine, indinavir, nelfinavir, ritonavir, saquinavir, adefovir, hydroxyurea, darunavir); [0248] beta-adrenoceptor blocking agents (atenolol, carvedilol, metoprolol, nebivolol, propanolol); [0249] cardiac inotropic agents (amrinone,

digitoxin, digoxin, milrinone), [0250] corticosteroids (beclomethasone dipropionate, betamethasone, budesonide, dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone, triamcinolone); [0251] disinfectants (chlorhexidine); [0252] diuretics (acetazolamide, frusemide, hydrochlorothiazide, isosorbide); [0253] enzymes; [0254] essential oils (anethole, anise oil, caraway, cardamom, cassia oil, cineole, cinnamon oil, clove oil, coriander oil, dementholised mint oil, dill oil, eucalyptus oil, eugenol, ginger, lemon oil, mustard oil, neroli oil, nutmeg oil, orange oil, peppermint, sage, spearmint, terpineol, thyme); [0255] gastro-intestinal agents (cimetidine, cisapride, clebopride, diphenoxylate, domperidone, famotidine, lansoprazole, loperamide, loperamide oxide, mesalazine, metoclopramide, mosapride, nizatidine, norcisapride, olsalazine, omeprazole, pantoprazole, perprazole, prucalopride, rabeprazole, ranitidine, ridogrel, sulphasalazine, esomeprazole); [0256] haemostatics (aminocaproic acid); [0257] lipid regulating agents (atorvastatin, lovastatin, pravastatin, probucol, simvastatin, rosuvastatin); [0258] local anaesthetics (benzocaine, lignocaine), [0259] opioid analgesics (buprenorphine, codeine, dextromoramide, dihydrocodeine, hydrocodone, oxycodone, morphine); [0260] parasympathomimetics and anti-dementia drugs (leteprinim, eptastigmine, galantamine, metrifonate, milameline, neostigmine, physostigmine, tacrine, donepezil, rivastigmine, sabcomeline, talsaclidine, xanomeline, memantine, lazabemide); [0261] peptides and proteins (antibodies, becaplermin, cyclosporine, erythropoietin, immunoglobulins, insuline, growth factors, botulinum toxin, infliximab); [0262] sex hormones (oestrogens: conjugated oestrogens, ethinyloestradiol, mestranol, oestradiol, oestriol, oestrone; progestogens; chlormadinone acetate,

cyproterone acetate, 17-deacetyl norgestimate, desogestrel, dienogest, dydrogesterone, ethynodiol diacetate, gestodene, 3-keto desogestrel, levonorgestrel, lynestrenol, medroxy-progesterone acetate, megestrol, norethindrone, norethindrone acetate, norethisterone, norethisterone acetate, norethynodrel, norgestimate, norgestrel, norgestrienone, progesterone, quingestanol acetate); [0263] stimulating agents (sildenafil, tadalafil, apomorphine, vardenafil); [0264] vasodilators (amlodipine, buflomedil, amyl nitrite, diltiazem, dipyridamole, glyceryl trinitrate, isosorbide dinitrate, lidoflazine, molsidomine, nicardipine, nifedipine, oxypentifylline, pentaerythritol tetranitrate); [0265] their N-oxides, their pharmaceutically acceptable acid or base addition salts or their stereochemically isomeric forms, etc.

Applicant argues that paclitaxel is not a basic drug compound.

The Examiner finds this argument unpersuasive, because CHEN1 specifically teaches "the paclitaxel solubilizers of the invention can be used to solubilize, distribute, and administer, but not limited to, other cancer and cancer-related pharmaceuticals, such as cisplatin", wherein cisplatin is a basic drug.

Applicant argues that Chen I does not disclose or enable a solid or semi-solid composition. The Examiner attempts to point to a general disclosure as support that Chen I does disclose such a composition, see, e.g., column 16, lines 11 - 18. This disclosure, however, is not sufficient to enable one of ordinary skill in the art to arrive at the currently claimed invention. Nowhere in Chen I is it disclosed that a basic drug compound in the presence of an acid can be formulated into a solid or semi-solid formulation.

The Examiner finds this argument unpersuasive, because lyophilization of cancer drugs used for injections are well known in the prior art, wherein the lyophilization prolong the stability of the drug. CHEN1 teaches solids, such as lyophilized solids, are well known in the art (see CHEN 1 at col. 16, line 11-18) and Applicant's specification at [0578]).

Applicant argues that Chen I is directed to formulations of paclitaxel, which, as discussed above, is not a basic drug. While the specification of Chen I provides a laundry list of compounds, including cisplatin or bicalutamide, nothing in Chen I suggests that one of ordinary skill in the art could arrive at the currently claimed invention. Such a reference does not provide "strong motivation to use other cancer drugs." (Office Action at 6). Furthermore, Chen I actually teaches away from the presently claimed invention. As discussed above, paclitaxel is not basic, and thus, the meaning of the presence of citric acid differs from what this means in the currently claimed invention. Neither Fais nor Casodex cure the deficiencies of
Chen I. These references merely provide information that cisplatin and bicalutamide are weak basic drugs. Fais and Casodex do not provide any disclosure or suggestion to allow one of ordinary skill in the art to modify the formulation disclosed in Chen I to arrive at the presently claimed formulation.

The Examiner finds this argument unpersuasive, because CHEN1 specifically teaches "the paclitaxel solubilizers of the invention can be used to solubilize, distribute, and administer, but not limited to, other cancer and cancer-related pharmaceuticals,

such as cisplatin, wherein cisplatin is a basic drug. This is a strong motivation to use other cancer drugs, such as cisplatin.

Applicant argues that Chen II teaches that improved dispersion and dissolution performance can be achieved by adding a surfactant to a pharmaceutical composition that comprises a drug compound and an amine. (col. 15, lines 45-60, col. 15, line 61-col. 16, line 28). While Vitamin E TPGS is identified as a compound having surfactant properties, Chen II attributes the improved bioavailability of the formulation to the amine in the formulation. Col. 15, lines 45-60, col. 41, lines 33-35. Thus, Chen II actually teaches away from using Vitamin E TPGS, which is a physiologically tolerable water-soluble acid.

The Examiner finds this argument unpersuasive, because CHEN2 specifically teaches using Vitamin-E TPGS to improve the dispersion and dissolution of the drugs (see col. 15, line 45-60), and specifically used the Vitamin-E TPGS in the examples. Thus, CHEN2 does not teach away from using Vitamin-E TPGS.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618